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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To regulate pancreatic islets for transplantation as organs.

IN THE HOUSE OF REPRESENTATIVES

Mr. ROSENDALE introduced the following bill; which was referred to the
Committee on _____

A BILL

To regulate pancreatic islets for transplantation as organs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Increase Support for
5 Life-saving Endocrine Transplantation Act” or the
6 “ISLET Act”.

7 **SEC. 2. REGULATION OF ISLET TRANSPLANTS.**

8 (a) IN GENERAL.—Section 374(d)(2) of the Public
9 Health Service Act (42 U.S.C. 274b(d)(2)) is amended by
10 inserting “pancreatic islets,” after “pancreas,”.

1 (b) CLARIFICATION.—Notwithstanding any other
2 provision of law, none of the following terms includes pan-
3 creatic islets:

4 (1) The term “drug”, as defined in section
5 201(g) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 321(g)).

7 (2) The term “biological product”, as defined in
8 section 351(i) of the Public Health Service Act (42
9 U.S.C. 262(i)).

10 (3) The term “human cells, tissues, or cellular
11 or tissue-based products (HCT/Ps)”, as defined in
12 section 1271.3 of title 21, Code of Federal Regula-
13 tions (or any successor regulations).

14 (c) REGULATIONS.—

15 (1) IN GENERAL.—Not later than 1 year after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services (referred to in this sec-
18 tion as the “Secretary”) shall update regulations
19 promulgated under parts F, G, and H of title III of
20 the Public Health Service Act (42 U.S.C. 262 et
21 seq., 264 et seq., 273 et seq.) and the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),
23 and such other regulations as the Secretary deter-
24 mines appropriate, to carry out the amendment
25 made by subsection (a).

1 (2) REPORT.—Not later than 6 months after
2 the date of enactment of this Act, the Secretary
3 shall report to Congress on the progress made in up-
4 dating regulations as required under paragraph (1).